

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER      74941**

**MICROBIOLOGY REVIEW(S)**

OFFICE OF GENERIC DRUGS, HFD-648

Microbiologist's Review #3

February 6, 1998

ANDA 74-941

APPLICANT: Abbott Laboratories  
200 Abbott Park Road  
Abbott Park IL 60064-3500

Formerly: Sanofi Winthrop

PRODUCT NAMES: Diltiazem Hydrochloride Injection,  
mg/mL

DOSAGE FORM AND ROUTE OF ADMINISTRATION:  
5 mL and 10 mL Single-Dose Vials, Intravenous

METHOD(S) OF STERILIZATION:

PHARMACOLOGICAL CATEGORY: Vasodilator

DATE OF INITIAL SUBMISSION: September 27, 1996  
(Received, September 30, 1996)

DATE OF FAX AMENDMENT: January 22, 1998  
Subject of this Review (Received, January 22, 1998)

RELATED DOCUMENTS: I

ASSIGNED FOR REVIEW: 2/6/98

REMARKS: The amendment provides for a the response to the microbiology deficiencies in the letter dated December 22, 1997 (originally for Sanofi-Winthrop).

CONCLUSIONS: The submission is recommended for approval on the basis of sterility assurance. The specific comments regarding the filling process are provided in "E. Review Notes".

/S/ 1/9/98  
Andrea S. High, Ph.D.

2/17/98

G. White

2/

OFFICE OF GENERIC DRUGS, HFD-640  
Microbiologist's Review #1  
January 8, 1997

A. 1. ANDA 74-941

APPLICANT

2. PRODUCT NAMES: Diltiazem Hydrochloride Injection, 5  
mg/mL.

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:  
5 mL and 10 mL Single-Dose Vials, Intravenous

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Vasodilator

B. 1. DATE OF INITIAL SUBMISSION: Subject of this Review  
September 27, 1996

(Received, September 30, 1996)

[Originally received, August 15, 1996/Refuse-to-File]

2. DATE OF AMENDMENT: None

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW:

C. REMARKS: The subject drug is aseptically filled into 5 mL  
and 10 mL vials on the filling line of the  
McPherson, Kansas pharmaceutical manufacturing  
facility.

D. CONCLUSIONS: The submissions are not recommended for  
approval on the basis of sterility assurance.  
The specific comments regarding the  
filling process are provided in "E. Review  
Notes" and "Microbiologist's Draft of Letter  
to Applicant".

/S/ 1/8/97  
Andrea S. High, Ph.D.